

**United States Court of Appeals**  
**FOR THE EIGHTH CIRCUIT**

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No. 05-3313

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Missouri Board of Examiners for  
Hearing Instrument Specialists,

Plaintiff-Appellee,

v.

Hearing Help Express, Inc.,

Defendant-Appellant.

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Appeal from the United States  
District Court for the Western  
District of Missouri.

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Submitted: April 17, 2006

Filed: May 11, 2006

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Before MURPHY, MELLOY, and GRUENDER, Circuit Judges.

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MURPHY, Circuit Judge.

The Missouri Board of Examiners for Hearing Instrument Specialists (the Board) brought this action against Hearing Health Express (Hearing Express), an Illinois corporation, to enjoin it from selling hearing aids to residents of Missouri without the prior fitting or testing required by state law. Hearing Express argued in response that the Missouri statute was preempted by the Medical Devices Amendment to the Federal Food, Drug and Cosmetic Act and that it violated the dormant Commerce Clause. Both parties moved for summary judgment. The district court granted the Board's motion and issued a permanent injunction. Hearing Express appeals, and we reverse.

Hearing Express is an Illinois corporation that is in the business of selling hearing aids through the mail and on the internet, including sales to customers in Missouri. It has no employees or facilities in Missouri and conducts all of its business with Illinois licensed hearing aid dispensers. It is undisputed that Hearing Express conducts its business in full compliance with the applicable federal law and regulations, which require either a presale hearing evaluation by a physician or a signed waiver of such an evaluation from the consumer seeking a hearing aid.

The state of Missouri regulates the sale of hearing instruments within its borders under Missouri Statute § 346.110(1). This statute prohibits the sale of hearing aids through the mail without prior fitting and testing by a Missouri licensed hearing instrument specialist, and it does not contain a written waiver option. In March 2002 the Central Investigations Unit of the Missouri Division of Professional Registration (CIU) purchased a hearing aid from Hearing Express using a fictitious name. The CIU received the hearing aid without a prior fitting or testing by a Missouri licensed specialist as required by the state statute. In February 2004 the Board sued Hearing Express in state court seeking both a preliminary and a permanent injunction. Hearing Express removed the case to the federal district court on the grounds that the Missouri statute is preempted by the Medical Devices Amendment (MDA), 21 U.S.C. § 360(k), to the Federal Food, Drug and Cosmetic Act (the Act) and that it violates the Commerce Clause. Both parties then moved for summary judgment.

The district court granted summary judgment in favor of the Board and permanently enjoined Hearing Express from selling hearing aids in Missouri without complying with the Missouri statute. The district court did not consider § 360k(a) to be an express preemption statute and concluded that it is not preempted by the MDA because the state requirements for fitting procedures are not covered by the federal law, relying on Smith v. Pingree, 651 F.2d 1021 (5th Cir. 1981). The district court also ruled that the Missouri statute does not violate the Commerce Clause since it regulates evenhandedly and its burdens on interstate commerce do not outweigh the

benefits to consumers or the state interest in regulating professionals within its borders. This appeal followed.

Hearing Express contends on its appeal that the Missouri statute is preempted by the MDA and regulations promulgated under it because the state law falls directly within the express preemption language of the federal statute. Hearing Express asserts that the Food and Drug Administration (FDA), acting under the authority delegated to it by Congress, has specifically rejected any requirement for mandatory audiological evaluations before the sale of hearing aids. See 45 Fed. Reg. 67329-67330. Appellant also points out that after the passage of the MDA, the FDA concluded that statutes which require mandatory audiological evaluations are preempted and it denied exemptions from the MDA's preemptive reach to states with statutes similar to Missouri's. Id. at 67329-67336. The Board responds that the district court correctly concluded that the Missouri law is not preempted because the federal statute does not regulate the fitting and testing of hearing aids. Appellee urges that the judgment be affirmed. We review challenges to summary judgment de novo, taking the record in the light most favorable to the responding party. Larson v. Kempker, 414 F.3d 936, 939 (8th Cir. 2005).

A state law may be either expressly or impliedly preempted by federal law. Express preemption exists when a federal law explicitly prohibits state regulation in a particular field. Implied preemption arises when a federal law completely occupies the field of regulation so that by implication there is no room for state regulation and the coexistence of federal and state regulation is not possible. See Chapman v. Lab One, 390 F.3d 620, 624 (8th Cir. 2004). Preemptive language in a statute is to be read narrowly, Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518-19 (1992), and without clear congressional intent there is a general presumption against finding implied preemption. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Cliff v. Payco General American Credits, Inc., 363 F.3d 1113, 1125 (11th Cir. 2004); Springston v. Consolidated Rail Corp., 130 F.3d 241, 244 (6th Cir. 1997). Implied preemption is

therefore rarely found and only when the state law is in direct conflict with or frustrates the purposes of the federal law. See, e.g., CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 78-79 (1987).

Whether the MDA preempts the Missouri statute depends upon the specific language used by Congress in drafting § 360k. Section 360k(a) of the MDA provides:

Except as provided in subsection (b)...no State...may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S. C. § 360k(a).

A state law will be preempted under MDA § 360k if any of its requirements (1) are "different from, or in addition to" those in the MDA and (2) "relate[] to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). Subsection (b) of the statute in turn provides that a state may petition the FDA for an exemption from its preemptive force. Since the language used in § 360k(a) expressly prohibits certain types of state regulation, we conclude this section of the MDA is an express preemption statute evincing congressional intent to prohibit states without a § 360k(b) exemption from regulating medical devices covered by the Act. See, e.g., McMullen v. Medtronic, Inc., 421 F.3d 482, 487 (7th Cir. 2005); Brooks v. Howmedica, Inc., 273 F.3d 785, 792 (8th Cir. 2001); New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795, 809 (N.J. 1978); 45 Fed. Reg. at 67328.

The Missouri statute at issue provides that "[n]o person shall (1) sell through the mails, hearing instruments without prior fitting and testing by a hearing instrument

specialist." Mo. Stat. § 346.110(1). A hearing instrument specialist is defined as "a person licensed by the state...who is authorized to engage in the practice of fitting hearing instruments." Mo. Stat. § 346.010(6).

The Board does not seriously dispute that the requirements of the Missouri statute are different from or in addition to those found in the MDA. Under the applicable federal regulations a customer wishing to purchase a hearing aid must either undergo an auditory evaluation or provide a signed waiver. 21 C.F.R. § 801.421(a). An auditory examination is thus optional under the MDA. See 45 Fed. Reg. 67328-67330. The Missouri statute contains no option for a customer to submit a waiver in lieu of an auditory examination. If acts which are permitted under the federal scheme are made mandatory by the state, that requirement is "in addition to the federal requirement." McMullen, 421 F.3d at 489; 45 Fed. Reg. at 67327. Although the Board claims that persons over eighteen can waive the requirement of an auditory exam, the text of the Missouri statute provides no such option. We conclude that the requirements in the Missouri statute are "different from or in addition to" those prescribed by the MDA.

The second inquiry is whether the Missouri statute relates to the safety or effectiveness of the device or any other requirement of the MDA. The FDA has concluded that a state requirement "of audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid." 45 Fed. Reg. at 67327. Moreover, the Board's own witnesses admitted in deposition testimony that the Missouri statute is related to the health of the patient and the effectiveness of the device.

The Board nevertheless argues that the Missouri statute is not preempted because it deals only with fitting and testing, which it says is not regulated by the MDA. The Board relies upon a 1981 Fifth Circuit decision dealing with a since repealed Florida statute which required certain minimum procedures and equipment

in the fitting of hearing aids. Pingree, 651 F.3d at 1023-24. The Fifth Circuit concluded that the Florida law dealt only with the mechanics of fitting rather than presale testing and that it was not preempted because the federal regulations "did not address the mechanics of fitting hearing aids to patients." Id. at 1024. We might question whether Congress made so broad an "implied reservation of power" to the states as Pingree suggests, id., but there are in any event significant distinctions between the repealed Florida law and Missouri statute. One element of the Florida law required that audiometric tests be conducted in a certified testing room with sound pressure levels at specified frequencies, but unlike the Missouri statute it allowed consumers to waive the requirement. Fl. Stat. § 468.135(7) (quoted in Pingree, 651 F.3d at 1023). The Florida law also had no mandatory testing requirement in contrast to the Missouri statute which mandates presale testing without exception.

We conclude that the requirements of Mo. Stat. § 346.110(1) are in addition to the federal requirements applicable to the sale of hearing aids and that they directly relate to the safety of consumers and the effectiveness of the devices. The Missouri statute therefore "interfere[s] with the execution and accomplishment of the objectives of the FDA's hearing aid regulation," 45 Fed. Reg. at 67327, and must be deemed preempted by the MDA. Because of this conclusion it is not necessary to consider any issues raised under the dormant Commerce Clause.

For these reasons the judgment and injunction are vacated and the case is remanded to the district court for entry of judgment in favor of Hearing Health Express.